

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE ORAL SODIUM PHOSPHATE
SOLUTION-BASED PRODUCTS
LIABILITY LITIGATION**

) **CASE NO. 1:09-SP-80000,**
) **(MDL DOCKET NO. 2066)**
)
) **THE HONORABLE ANN ALDRICH**
)
) **MASTER CONSOLIDATED**
) **COMPLAINT FOR INDIVIDUALS**
)
) **JURY DEMAND ENDORSED HEREIN**
)

Plaintiffs bring this Master Complaint for Individual Plaintiffs against Defendant C.B. Fleet Company, Inc., for injuries sustained as a result of the fault and wrongful conduct of Defendant as set forth herein related to the manufacture, design, sale, supply, marketing, promotion, warranties, and warnings and instructions of Fleet Phospho-soda. Plaintiffs complain of Defendant and allege as follows:

PARTIES

1. This Master Complaint for Plaintiffs is brought on behalf of all individual plaintiffs, or deceased plaintiffs, who ingested Fleet Phospho-soda, also known or marketed as Fleet Phospho-soda Accu-Prep or Fleet Phospho-soda EZ-Prep.

2. Defendant C.B. Fleet Company, Inc. ("Fleet" or "Defendant") is a citizen of the State of Virginia, with its corporate headquarters located in Lynchburg, Virginia.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332, in that this is a civil action between citizens of different states and the matter in controversy exceeds the sum of \$75,000, exclusive of interests and costs. This complaint is drafted and filed in the Northern District of Ohio in accordance with Case Management Order No. 1 entered on or

about November 24, 2009 in MDL 2066.

4. Venue is proper in this judicial district pursuant to a stipulation from Defendant that it will not assert any objection of improper venue pursuant to Fed. R. Civ. P. 12(b) in any case filed directly in the Northern District of Ohio that would have otherwise been properly transferable to this Multi-District Litigation proceeding and for which the original venue would have otherwise been proper in a district court outside the Northern District of Ohio, and pursuant to Case Management Order No. 1. Transfer to and consolidation for pre-trial purposes to this venue is proper under 28 U.S.C. Section 1407 and the Transfer Order of the United States Judicial Panel on Multidistrict Litigation, In re Oral Sodium Phosphate Solution-Based Products Liability Litigation, MDL 2066, entered on or about June 23, 2009. Upon the completion of all MDL pretrial proceedings applicable to this case, plaintiff in each individual case reserves the right to seek remand of this case for trial to the United States District Court for the jurisdiction where the individual plaintiff's case arose, which district is the proper venue under 28 U.S.C. § 1391 (a & c) because the events giving rise to the claims occurred within said district and because Defendant conducts business within that district, and has engaged in promoting, manufacturing, marketing, and/or distributing goods and products to consumers in that district.

5. At all times relevant, Defendant manufactured, created, designed, tested, labeled, packaged, supplied, marketed, sold, advertised, and/or otherwise distributed in interstate commerce an over-the-counter ("OTC") product known as Fleet Phospho-soda.

COMMON FACTUAL ALLEGATIONS

6. Fleet Phospho-soda is an over the counter ("OTC") product used as a laxative or bowel purgative. It is in a category of products generically referred to as oral sodium phosphate solution-based products ("OSPS").

7. A single dose of Fleet Phospho-soda (20-45mL) has long been used as a laxative to alleviate occasional constipation.

8. Forty-five (45) mL of Fleet Phospho-soda contains 8.1g of dibasic sodium phosphate and 21.6g of monobasic sodium phosphate.

9. The United States Food & Drug Administration's ("FDA") Tentative Final Monograph ("TFM") for Laxative Products as it pertains to OSPA provides for a maximum oral dose of 7.56g of dibasic sodium phosphate and 20.2g of monobasic sodium phosphate in 24-hours. The term "laxative", as used in the TFM and as used by Fleet, includes use of Fleet Phospho-soda as a bowel purgative or bowel cleanser.

10. On and before December 11, 2008, Fleet promoted the use of two 45-mL doses of Fleet Phospho-soda, separated by as little as 5 hours, as a safe and effective bowel cleansing regimen in preparation for colonoscopy and other medical procedures.

11. Ninety (90) mL of Fleet Phospho-soda contains 16.2g of dibasic sodium phosphate and 43.2g of monobasic sodium phosphate, more than double the maximum oral dose of OSPA generally recognized as safe and effective by the FDA's TFM for Laxative Products.

12. Fleet has sought but failed to obtain an amendment of the TFM for Laxative Products to include a dosing regimen of Fleet Phospho-soda consisting of two 30-mL to 45-mL doses separated by less than 24 hours.

13. Fleet designed, publicized, promoted and recommended to consumers and physicians that the standard dose of Fleet Phospho-soda to be used as a bowel purgative or cleanser was two 45-mL doses separated by 10 to 12 hours (the "Double Dose").

14. The FDA has repeatedly advised Fleet that the data upon which it relied in seeking to amend the TFM to allow the Double Dose was insufficient to demonstrate the safety of more than a single 45-mL dose of sodium phosphate oral solution in a 24-hour period.

15. The FDA has never amended the TFM to allow the Double Dose as requested by Fleet.

16. On December 11, 2008, the FDA again denied Fleet's citizen petition to amend the TFM to allow Fleet's Double Dose regimen due to the dangers of acute renal injury.

17. On December 11, 2008, Fleet issued a voluntary recall of Fleet Phospho-soda.

18. Since at least 1992, Fleet has received numerous reports of serious injury, including acute phosphate nephropathy, acute renal failure, chronic kidney disease, and death following the use of more than a single 45-mL dose of Fleet Phospho-soda in a 24 hour period.

19. At all relevant times, Defendant knew or should have known that taking more than a single 45-mL dose of Fleet Phospho-soda in a 24 hour period could cause serious physical injury, including acute renal failure and chronic kidney disease, in persons such as plaintiffs.

20. Prior to December 11, 2008, Fleet suppressed information on and/or downplayed the risks of acute phosphate nephropathy, acute renal failure, and chronic kidney disease following the use of more than a single 45-mL dose of Fleet Phospho-soda in a 24-hour period.

21. Prior to December, 11, 2008, Fleet falsely reassured physicians that taking two 45-mL doses of Fleet Phospho-soda, separated by less than 24 hours, provides safe bowel cleansing for any patient not specifically contraindicated.

22. At certain times, Fleet suggested certain persons use the "Double Dose" with "caution", but failed to adequately describe what was meant by this suggestion, and implicitly or explicitly represented that if the patient had no pre-existing and known kidney insufficiency, and/or creatinine clearance was within normal limits, then use of the Double Dose was safe for such individuals.

23. Defendant, having placed Fleet Phospho-soda in the stream of commerce, was under a duty of reasonable care to give adequate warning of any dangers known to it or which in the use of reasonable care it should have known and which a user of Fleet Phospho-soda ordinarily would not discover, and to use reasonable care to design a product to avoid unreasonable risk of injury from the use of the product for its intended purpose.

24. Prior to December 11, 2008, Fleet was aware that doctors were routinely directing patients to use Fleet Phospho-soda in accordance with Fleet's recommended Double Dose.

25. Prior to December 11, 2008, the relevant entries by Fleet in the Physicians Desk Reference (PDR) failed to adequately warn about the health risks of acute renal failure and chronic kidney disease, or any other risk of serious injury, associated with the use of the Double Dose.

26. Prior to December 11, 2008, the relevant entries by Fleet in the PDR advised doctors to use the Double Dose of Fleet Phospho-soda in less than 24 hours, and cited as proof of the safety of the Double Dose the dosing regimens described in six different medical articles – all utilizing the Double Dose with a dosing interval of less than 24 hours and one using a dosing interval as short as six hours.

27. Fleet knew or should have known that doctors do not regularly consult the PDR for information on OTC products such as Fleet Phospho-soda.

28. Since at least 1996, Fleet was on notice that the studies it relied upon and cited in the PDR and in other published medium as proof of clinically established safety were scientifically inadequate to prove safety, were underpowered, and in fact did not justify the claims of safety made by Fleet.

29. Starting at some time in mid-2005, Fleet published information in the PDR suggesting that a range of doses from 30-mL to 45-mL might be advisable in certain circumstances, or in patients for whom Fleet suggested use the product "with caution", but Fleet failed to adequately explain what it meant by use "with caution", downplayed the risks, and implicitly or explicitly stated that the standard Double Dose was appropriate if creatinine clearance was within normal limits.

30. In 2003, Defendant also began selling Phospho-soda under the name of Fleet Phospho-soda ACCU-PREP. For purposes of this Complaint, all allegations as to Fleet's

wrongful acts and omissions and the Double Dose apply to Fleet Phospho-Soda ACCU-PREP, except that each 45-mL dose was split into three 15-mL doses taken fifteen minutes apart, and the division of the 45-mL dose as described was done for purposes of palatability, or taste, and not for purposes of increasing patient safety.

31. In 2006 Fleet also began selling a Phospho-soda under the name Fleet Phospho-soda EZ-Prep, consisting of one 30-mL dose and one 45 mL dose. For purposes of this Complaint, all allegations as to Fleet's wrongful acts and omissions and the Double Dose apply to Fleet Phospho-soda EZ Prep, with the exception that the dosing is not two 45-mL doses, but is one 45-mL dose followed by one 30-mL dose, both of which are consumed in less than a 24 hour period.

32. The ingredients in Fleet Phospho-soda are absorbed into the blood stream.

33. At all times relevant, Fleet knew or should have known that use of Fleet Phospho-soda in the Double Dose can cause soft tissue calcification, primarily in the kidneys, heart, blood vessels, cornea, lungs, and gastric mucosa.

34. Efficacious and safer alternative bowel purgatives, which are not absorbed into the blood stream, are commercially available, and at all times relevant, Fleet made and marketed such products.

35. At all times relevant, bowel purgatives that are efficacious and safer, and work with smaller amounts of dibasic and monobasic sodium phosphate, were commercially available.

36. At all times relevant, bowel purgative kits which better control and ensure proper hydration were commercially available.

37. At all times relevant, Fleet knew or should have known that adequate hydration before, during and after use of Fleet Phospho-soda as a bowel purgative would be necessary to minimize or eliminate the risk of acute renal failure or other serious adverse effects.

38. Fleet never undertook any study to establish the amount of hydration that would be adequate when using the Double Dose to minimize or eliminate the risk of acute renal failure or other serious adverse effects.

39. Fleet arbitrarily selected a volume of fluids to be ingested with the Double Dose when it knew there was “no real science” behind the amount selected, but represented to consumers and physicians the amount it arbitrarily selected was adequate and safe.

40. The selection of the amount of hydration to be used was done for marketing purposes to allow Fleet to advertise its Double Dose as the “low volume alternative” in order to increase market share for its product.

41. Fleet knew or should have known that the glomerular filtration rate in humans tends to decrease with age.

42. The benefits of the use of the Double Dose of Fleet Phospho-soda as a bowel purgative are outweighed by the risk of serious injury, including renal failure.

43. The Double Dose fails to meet consumer expectations of safety when used as directed and recommended by Fleet as a bowel purgative.

44. Fleet, by designing, promoting, labeling and selling the Double Dose of Fleet Phospho-soda as a bowel purgative, falsely, deceptively and materially misrepresented to Plaintiff(s) that Fleet Phospho-soda was a safe product when, in fact, it was not safe for its intended use. For example, Defendant expressly misrepresented on the Fleet Phospho-soda packages that “[w]hen taken as directed,” Fleet Phospho-soda’s “laxative action is gentle, virtually free from the likelihood of gastrointestinal discomfort, or irritation, and is safe for the age groups indicated.”

45. Plaintiff was in one of the “indicated” age groups at the time plaintiff used Fleet Phospho-soda.

46. Despite its knowledge of the unsafe and dangerous nature of the Double Dose of Fleet Phospho-soda, Defendant recklessly, negligently and knowingly failed to provide needed, accurate, and adequate information regarding the health hazards of the Double Dose of Fleet Phospho-soda to those who would reasonably and foreseeably use the product as Fleet intended it be used. For example, Defendant failed to advise plaintiff of the proper amount of water or other liquids to consume to ensure adequate hydration when using the Double Dose of Fleet Phospho-soda as a bowel purgative, and otherwise failed to advise plaintiffs of the serious and permanent health risks and hazards associated with the use of the Double Dose of Fleet Phospho-soda.

47. Fleet intentionally omitted to state facts necessary to make the statements it did make not misleading and false. Among other omissions, Fleet never informed physicians or consumers that the Double Dose was not approved by the FDA, that the FDA had found the scientific studies Fleet relied upon for its claims of safety to be inadequate to establish the safety of the Double Dose, and Fleet did not advise consumers or physicians in the United States of the safety concerns about the Double Dose raised by the Australian Drug Advisory Board or Health Canada.

48. Defendant intended consumers, including plaintiffs, as well as medical professionals, to rely on Defendant's false representations and omissions regarding the safety of the Double Dose of Fleet Phospho-soda and the dangers and health risks associated with the product.

49. Defendant's false representations and omissions were negligently, recklessly or knowingly false and misleading as to plaintiffs, and were made with the intent of inducing plaintiffs into purchasing and using Fleet Phospho-soda.

50. Plaintiffs believed and justifiably relied upon Defendant's representations and misrepresentations and were thereby induced into purchasing and using Fleet Phospho-soda.

51. Plaintiffs purchased or were provided Fleet Phospho-soda ("the packages").

52. The packages of Fleet Phospho-soda contained no warnings regarding the health risks, including acute renal failure and chronic kidney disease, associated with the use of Fleet Phospho-soda when used by persons such as plaintiffs in accordance with the bowel cleansing regimen that Fleet was falsely promoting as safe and effective.

53. Plaintiffs used the Double Dose of Fleet Phospho-soda in accordance with and in reliance on the instructions and representations on the packages and in accordance with each plaintiff's doctor's recommendation, which recommendation was, on information and belief, informed by and made in reliance upon Fleet's false representations and omissions as to the safety of the Double Dose.

54. Plaintiffs used Fleet Phospho-soda for its intended or reasonably foreseeable purpose, *i.e.*, as a bowel purgative prior to a medical procedure.

55. Neither the Fleet Phospho-soda nor the warnings and instructions on the packaging in which it was contained were reasonably safe in their design in that the Double Dose of Fleet Phospho-soda was not reasonably safe for its intended or reasonably foreseeable use as a bowel purgative or bowel cleanser, as more than 45-mL of monobasic and dibasic sodium phosphate was designed to be ingested in less than 24 hours; the packages containing the product failed to adequately warn of various dangers and health risks, among them the risk of permanent kidney damage; and the packaging failed to provide adequate instructions on the safe use of the product, in that it failed to provide adequate and correct information on the amount of hydration necessary to use the product safely; and the packaging failed to disclose that Fleet had no real scientific basis for the amount of hydration it did instruct people to use with the Double Dose.

56. Plaintiffs underwent a medical procedure subsequent to using the Double Dose.

57. Following the medical procedure, each plaintiff has been diagnosed with acute kidney failure or other medical conditions directly caused by the use of Fleet Phospho-soda. These conditions are permanent.

58. As a direct and proximate consequence of the use of Fleet Phospho-soda, plaintiffs now suffers from chronic kidney disease, and other injurious conditions for which plaintiffs have in the past, or may in the future, require medical care and treatment, dialysis or a kidney transplant as a result of the injuries sustained from use of Fleet Phospho-soda. Plaintiffs have in the past and will in the future incur medical expenses and other economic loss, and has in past and will in the future experience pain, suffering, emotional distress, humiliation, disfigurement, embarrassment, loss of enjoyment of life, shortened life expectancy, and other damages. The injuries sustained by each plaintiff were caused by the use of the Double Dose of Fleet Phospho-soda.

59. Defendant knew or should have known of the dangers of Fleet Phospho-soda when used in accordance with the bowel cleansing regimen designed by Fleet and which Fleet falsely promoted as safe, including its propensity to cause kidney disease of the type sustained by plaintiff, but through its negligent, reckless, and fraudulent conduct Fleet concealed and failed to advise consumers, including plaintiffs, of the full extent of the dangers and health risks associated with the Double Dose of Fleet Phospho-soda.

60. Defendants knew or otherwise expected that the Fleet Phospho-soda would reach the ultimate user, including plaintiffs, without substantial change from, or alteration of, the condition in which it was originally manufactured and sold, including the packaging, warning, and instructions for use.

61. The amount of damages sought by each plaintiff exceeds the sum of Seventy-Five Thousand (\$75,000.00) Dollars, exclusive of interest and costs.

FIRST CAUSE OF ACTION
(Strict Liability – Failure to Warn)

62. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 61 of this Complaint as though set out in full.

63. As set forth above, the Double Dose of Fleet Phospho-soda that each plaintiff used was unreasonably dangerous and defective and not reasonably safe for use in its intended or reasonably foreseeable purposes because it did not have correct, adequate and complete warnings and instructions issued in language that was direct, unequivocal, and sufficiently forceful to adequately explain and warn of the hazards of the product or the way to use the product safely.

64. Fleet's sale, marketing, distribution, and supplying of a defective product to Plaintiff were a substantial factor in causing plaintiffs to suffer injuries and damages.

65. Each plaintiff has suffered and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, humiliation, disfigurement, embarrassment, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss, all in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

66. By reason of the foregoing, Defendant is strictly liable to each plaintiff.

67. Plaintiff is entitled to punitive damages because Defendant's conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's rights and the rights and safety of other users of Fleet Phospho-soda.

SECOND CAUSE OF ACTION
(Strict Liability- Design Defect)

68. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 67 of this Complaint as though set out in full.

69. As set forth above, the Double Dose of Fleet Phospho-soda was defectively designed as a bowel purgative in that it was unreasonably dangerous to consumers when used in a reasonably foreseeable manner, including the manner that was directed on the packages and recommended by Defendant.

70. There are available safer alternative bowel purgatives.

71. The benefit of the design and use of Fleet Phospho-soda as a bowel purgative (at the dosage and at the interval promoted by Fleet) is outweighed by the risk of serious injury, including permanent kidney injury, disease and death.

72. The design of the product is inconsistent with a consumer's reasonable expectations of safety when using the product as intended and directed by Fleet.

73. It would have been feasible to design the Fleet Phospho-soda in a way that would have eliminated or substantially diminished the risk of permanent kidney injury, disease, death, and other dangers and health risks known to Fleet.

74. Defendant breached its duty to design Fleet Phospho-soda as a bowel purgative in a reasonably safe manner and Fleet was otherwise at fault in the manner in which it promoted, marketed, advertised, and recommended the use of the Double Dose design.

75. As a direct and proximate consequence of the defective design of the Double Dose, each plaintiff suffered injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, humiliation, disfigurement, embarrassment, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss, all in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

76. Plaintiff is entitled to punitive damages because Defendant's failure to exercise reasonable care in designing Fleet Phospho-soda was wanton, grossly reckless, and/or in

conscious disregard of plaintiff's rights and the rights or safety of other users of Fleet Phospho-soda.

THIRD CAUSE OF ACTION
(Negligence)

77. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 76 of this Complaint as though set out in full.

78. Defendant knew or should have known that the design of the Double Dose of Fleet Phospho-soda was reasonably certain to be dangerous when used in a reasonably foreseeable manner as a bowel purgative, including the manner that was directed by Fleet on the packaging and in its other published material, including all communications and marketing directed to physicians and consumers.

79. Defendant breached its duty of reasonable care owed to plaintiff as set forth above by the manner in which it designed the Double Dose; in failing to give adequate warning of the dangers known to it or which in the use of reasonable care Fleet should have known and which a user of Fleet Phospho-soda ordinarily would not discover; and Fleet breached its duty of reasonable care to provide adequate instructions so the product could be used safely when used as intended.

80. Defendant was otherwise negligent in its marketing, promotion, advertising, and communications to consumers and health care professionals regarding the alleged safety of the Double Dose of Fleet Phospho-soda when used as directed or intended by Fleet as a bowel purgative.

81. As a direct and proximate consequence of Defendant's negligent acts, omissions, recklessness, and breach of duty, each plaintiff suffered injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, humiliation, disfigurement, embarrassment, as well as other general or non-economic damages, in addition to

past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss, all in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

82. Plaintiff is entitled to punitive damages because Defendants' negligence was wanton, grossly reckless, and/or in conscious disregard of Plaintiff's rights and the rights and safety of other users of the Double Dose of Fleet Phospho-soda.

FOURTH CAUSE OF ACTION
(Misrepresentation/consumer fraud)

83. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 82 of this Complaint as though set out in full.

84. Defendant's material misrepresentations and omissions to plaintiffs, other consumers, and medical professionals, as set forth more fully above, was a breach of Fleet's duty of reasonable care owed to plaintiffs to provide accurate and adequate information regarding the Double Dose of Fleet Phospho-soda and Fleet's duty to not misrepresent or conceal any dangers regarding the Double Dose of Fleet Phospho-soda known to Fleet or, which in the use of reasonable care, Fleet should have known.

85. Fleet further intentionally made the above misrepresentations and omissions, or made them without regard to their truth or falsity, or Fleet was negligent in making the material representations and omissions as set forth above in its marketing, promotion, advertising, and other communications to consumers and health care professionals regarding the alleged safety of the Double Dose of Fleet Phospho-soda when used as directed or intended by Fleet as a bowel purgative, all of which Fleet intended would be relied upon by consumers and health care professionals in making the decision to use the Double Dose of Fleet Phospho-soda as a bowel purgative in the manner recommended and directed by Fleet, and such misrepresentations and omissions were in fact relied upon to the detriment of plaintiffs.

86. As a direct and proximate result of Fleet's negligent or intentional misrepresentations, omissions, recklessness, negligence, fault, and breach of duty, each plaintiff suffered injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, humiliation, disfigurement, embarrassment, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss, all in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

87. Plaintiff is entitled to punitive damages because Defendant's acts and omissions were wanton, grossly reckless, and/or in conscious disregard of Plaintiff's rights and the rights and safety of other users of Fleet Phospho-soda.

88. To the extent the State where each plaintiff ingested the product allows by statute a cause of action for consumer fraud or deceptive or unfair business practices, each plaintiff asserts a violation of said statute(s), and prays for such relief, including attorney fees, as may be allowable pursuant to said statute(s).

FIFTH CAUSE OF ACTION
(Breach of Express Warranties)

89. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 88 of this Complaint as though set out in full.

90. Through advertising, labeling on the packages, and in other ways, Defendant made certain express warranties about the safety and appropriate uses of the Double Dose of Fleet Phospho-soda as a bowel purgative in order to induce the public and plaintiffs to purchase and use Fleet Phospho-soda, such as the warranties set forth above.

91. Defendant breached the express warranties because, among other things, the Double Dose of Fleet Phospho-soda was not safe for use as a bowel purgative; it was not safe for

use by the age groups indicated; and it was not safe when used in the manner directed by Fleet as a bowel purgative.

92. Through the use of reasonable care, plaintiffs could neither have discovered Defendant's breach nor realized the danger of using Fleet Phospho-soda as a bowel purgative.

93. As a direct and proximate result of Defendant's breach of the express warranties, each plaintiff suffered severe injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, humiliation, disfigurement, embarrassment, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss, all in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

SIXTH CAUSE OF ACTION
(Breach of Implied Warranty)

94. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 93 of this Complaint as though set out in full.

95. The law implies a warranty by manufacturers and companies in the chain of distribution who place a product on the market that it is merchantable and reasonably fit for the ordinary purposes for which such product is used.

96. As set forth above, Fleet Phospho-soda was not merchantable nor reasonably fit to be used for its ordinary purposes, and, accordingly, Defendant breached the implied warranties owed to Plaintiff.

97. As a direct and proximate result of Defendant's breach of the implied warranties, each plaintiff suffered severe injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, humiliation, disfigurement, embarrassment, as well as other general or non-economic damages, in addition to past and future

special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss, all in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

SEVENTH CAUSE OF ACTION

(Fraud & Deceit)

98. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 97 of this Complaint as though set out in full.

99. Defendant fraudulently represented to physicians, the public, and plaintiffs that the Double Dose of Fleet Phospho-soda separated by less than 24 hours was safe for use as a bowel purgative when, in fact, it was not reasonably safe.

100. Defendant fraudulently concealed and failed to advise plaintiffs and health care professionals of needed information and facts regarding the use of the Double Dose of Fleet Phospho-soda and of the health risks and hazards known by Fleet to be associated with and caused by use of the Double Dose of Fleet Phospho-soda as a bowel purgative.

101. Defendant's material misrepresentations and omissions were knowingly or recklessly false when made, or made with conscious disregard of their truth or falsity, and were made with the intent of inducing the public, health care providers, and plaintiffs into purchasing and using the Double Dose of Fleet Phospho-soda as a bowel purgative.

102. Plaintiffs and, on information and belief, plaintiffs' health care providers, believed and justifiably relied upon Defendant's fraudulent misrepresentations and omissions and were thereby induced into recommending, purchasing and using the Double Dose of Fleet Phospho-soda as a bowel purgative.

103. As a direct and proximate result of Defendant's fraudulent misrepresentations and omissions, as set forth above, each plaintiff suffered injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, humiliation,

disfigurement, embarrassment, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss, all in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

104. Even after plaintiffs purchased and used Fleet Phospho-soda, Defendant continued to fraudulently conceal the dangers and health risks of the Double Dose of Fleet Phospho-soda thereby inducing consumers and plaintiffs into believing the product was safe when, in fact, it was not.

105. Plaintiff is entitled to punitive damages because Defendant's conduct was wanton, grossly reckless, and/or in conscious disregard of Plaintiff's rights and the rights and safety of other users of Fleet Phospho-soda.

EIGHT CAUSE OF ACTION
(Loss of Consortium)

106. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 105 of this Complaint as though set out in full.

107. As to each plaintiff who was a married person on the date of ingestion of Fleet Phospho-soda, the wrongful acts and omissions of Fleet as set forth herein have caused harm to the spouse of such plaintiff, in that said spouse has been deprived of and has suffered a loss of care, comfort, companionship, love, affection, and services, and such loss will continue into the future, and each spouse has suffered and will continue to suffer emotional distress as a result of the injury to their husband or wife, and as a result of such damages the spouse of each plaintiff is entitled to compensatory damages in an amount in excess of \$75,000.

NINTH CAUSE OF ACTION
(Wrongful Death)

108. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 107 of this Complaint as though set out in full.

109. Decedent Plaintiffs ingested Fleet Phospho-soda in a manner recommended and designed by Defendant, and died as a direct and proximate result of the defects in Defendant's product, Defendant's negligence, fault, breach of warranty, fraud, and other wrongful acts and omissions as set forth above.

110. Decedent Plaintiff is survived by various family members, named and unnamed, all of whom have suffered a loss of care, comfort, companionship, support, society, services, marital association, consortium, and love as a direct and proximate result of the fault and other wrongful acts and omissions of Defendant which caused the death of Decedent Plaintiff.

111. Plaintiff is the personal representative of Decedent Plaintiff, and brings this wrongful death claim pursuant to the law of the State where Decedent Plaintiff died for all damages and claims cognizable under the law therein, including punitive damages, if so permitted by law.

112. The compensatory damages claimed exceed the sum of \$75,000, exclusive of interest and costs.

TENTH CAUSE OF ACTION
(Survival Action)

113. Plaintiffs repeat and reallege the allegation in paragraphs 1 – 112 of this Complaint as though set out in full.

114. Decedent Plaintiffs ingested Fleet Phospho-soda in a manner recommended and designed by Defendant, and died as a direct and proximate result of the defects in Defendant's product, Defendant's negligence, fault, breach of warranty, fraud, and other wrongful acts and omissions as set forth above.

115. Prior to the death of Decedent Plaintiff, as a direct and proximate result of the fault and other wrongful acts and omissions of Defendant as alleged above, said Decedent did suffer severe bodily injury, pain, anxiety, emotional distress, disfigurement, disability, mental

anguish, shortened life expectancy, loss of enjoyment of life, loss of income or earning capacity, medical expenses, and other general and special damages, all in an amount in excess of \$75,000 dollars.

116. Plaintiff is the personal representative of the Decedent Plaintiff, and brings this Survival Action pursuant to the law of the State where said Decedent died for all damages and claims cognizable or authorized under the laws of said jurisdiction, including, if allowed, all pre-death pain and suffering damages and other damages sustained by said Decedent prior to death, and punitive damages, if allowed.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff(s) demands judgment on each of the causes of action alleged for general and special damages, and punitive damages, in such amounts in excess of \$75,000 as will be proven at trial, and further prays for an award of reasonable attorneys' fees and costs, together with such other and further relief as may be deemed just, equitable, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury on all issues so triable.

DATED: December 22, 2009

Respectfully submitted, on Behalf of all Plaintiffs,
By the Plaintiffs' Executive Committee, as Authorized by
Case Management Order No. 1.

/s/ John R. Climaco
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CERTIFICATE OF SERVICE

A copy of this Plaintiffs' Master Consolidated Complaint for Individuals was filed electronically on December 22, 2009. The parties may access this filing through the courts CM/ECF system.

/s/ Dawn M. Chmielewski
Dawn M. Chmielewski